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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/632,991 | 08/01/2003 | Herbert L. Berman | VVMDNZ00201 | 8976 |

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LEVINE BAGADE HAN LLP
2483 EAST BAYSHORE ROAD, SUITE 100
PALO ALTO, CA 94303

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| EXAMINER |
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WINAKUR, ERIC FRANK

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| ART UNIT | PAPER NUMBER |
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3768

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06/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/632,991

Applicant(s)

BERMAN ET AL.

Examiner

Eric F. Winakur

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-31 and 33-50 is/are pending in the application.
- 4a) Of the above claim(s) 37-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-31, 33-36 and 45-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claims 29 - 31, 33 - 36, and 45 - 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what the phrase "a non-invasive glucose monitor device having an analyte measurement generator that calculates blood glucose levels obtained from a skin surface" is meant to define. While measurements may be obtained from a skin surface and calculated values may correlate with blood glucose levels present on a skin surface, the claim recites the phrase "calculates blood glucose levels obtained from a skin surface" which is not precisely indicative of either of these interpretations. As such, the scope of the claimed subject matter is not clearly defined.

Claim Rejections - 35 USC § 103

3. Claims 29, 30, 33 - 36, and 45 - 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinonen '020 (previously cited) in view of Heinonen '586 (previously cited) and Rosenthal (previously cited) for the reasons set forth in paragraphs 8 and 9 of the Office action mailed 4 October 2006.

4. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heinonen '020, Heinonen '586, and Rosenthal as applied to claim 29 above, and further in view of Mault (previously cited). The combination, in particular Heinonen '020

(column 1, lines 50 - 65), teaches using data relating to physical strain in calculation of the glucose level of the subject, but do not particularly teach obtaining this information with a sensor. Mault, see Figure 15 embodiment and the description thereof, teach that an apparatus may include an activity sensor for measuring parameters related to activity of a subject. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination to include an activity sensor, as taught by Mault, since the combination requires information related to physical strain of a subject and Mault teaches one manner to obtain this required information.

Response to Arguments

5. Applicant's arguments filed 4 April 2007 have been fully considered but they are not persuasive. Applicant contends that the combination of Heinonen '020, Heinonen '586, and Rosenthal does not teach "an analyte measurement generator which calculates the blood glucose level present on a user's skin that is placed against the device" (remarks, page 6 of 7). However, it is noted that the claim merely requires an analyte measurement generator that calculates blood glucose levels obtained from a skin surface of the patient. This phrase is somewhat unclear, as described in paragraph 2 above, and is of a different scope than what Applicant argues in the remarks. In particular, as the measurements performed by the combination are obtained non-invasively with a sensor positioned on the skin surface of the patient, the combination of Heinonen '020, Heinonen '586, and Rosenthal is considered to meet the claim limitations.

Conclusion

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6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art teaches several techniques for non-invasively measuring a subject's glucose level at their skin surface. See, for example, Peck, Sembrowich et al., Schroeder et al., Kurnik et al., Tamada, and Uchida et al.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571/272-4740. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Eric F Winakur
Primary Examiner
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